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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,128

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Yen Choo

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06/25/2008

MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER

TONGUE, LAKIA J

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

06/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,128	Applicant(s) CHOO, YEN	
	Examiner LAKIA J. TONGUE	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2 and 4-16, drawn to a method for determining the effect of a plurality of culture conditions on a cell, comprising the steps of: (a) providing a first set of groups of cell units each comprising one or more cells, and exposing said groups to desired culture conditions; (b) subdividing one or more of said groups to create a further set of groups of cell units; (c) exposing said further groups to further desired culture conditions; (d) optionally, repeating steps (b) - (c) iteratively as required; and (e) assessing the effect on a given cell unit of the culture conditions to which it has been exposed.

Group II, claim(s) 3 and 5-16, drawn to a method for exposing a cell to a variety of cell culture conditions, comprising the steps of: a) providing a first set of groups of cell units each comprising one or more cells, and exposing said groups to desired culture conditions; (b) pooling two or more of said groups to form at least one second pool; (c) subdividing the second pool to create a further set of groups of cell units; (d) exposing said further groups to desired culture conditions; and (e) optionally, repeating steps (b) - (d) iteratively as required.

Group III, claim(s) 17, 18 and 29, drawn to a method for identifying a gene which influences a cellular process, comprising the steps of: a) determining the effect of one or more culture conditions on a cell unit, in accordance with any one of the preceding claims; b) analyzing gene expression in said cell units when exposed to said culture conditions; and c) identifying genes which are differentially expressed under desired culture conditions

Group IV, claim(s) 19 and 29, drawn to a method for producing a nucleic acid which encodes a gene product which influences a cellular process, comprising identifying a gene in accordance with a method for identifying a gene which influences a cellular process, comprising the steps of: a) determining the effect of one or more culture conditions on a cell unit; b) analyzing gene expression in said cell units when exposed to said culture conditions; and c) identifying genes which are differentially expressed

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under desired culture conditions and producing at least the coding region of said gene by nucleic acid synthesis or biological replication.

Group V, claim(s) 20-22 and 29, drawn to a method for inducing a cellular process, comprising the steps of: identifying one or more genes which are differentially expressed in association with the cellular process and modulating the expression of said one or more genes in the cell.

Group VI, claim(s) 23-25 and 29, drawn to identifying the state of a cellular process.

Group VII, claim(s) 26 and 29, drawn to methods of inducing a cellular process comprising determining the effect of one or more culture conditions and exposing cells to the culture conditions that would induce said cellular process.

Group VIII, claim(s) 27 and 29, drawn to a method for identifying an agent which is capable of inducing a cellular process, comprising the steps of: 1) determining the effect of one or more agents on a cell unit, a method for determining the effect of a plurality of culture conditions on a cell, comprising the steps of: (a) providing a first set of groups of cell units each comprising one or more cells, and exposing said groups to desired culture conditions; (b) subdividing one or more of said groups to create a further set of groups of cell units; (c) exposing said further groups to further desired culture conditions; (d) optionally, repeating steps (b) - (c) iteratively as required; and (e) assessing the effect on a given cell unit of the culture conditions to which it has been exposed; and 2) identifying those agent(s) which induce the cellular process in the cell units.

Group IX, claim(s) 28 and 29, drawn to a method for preparing an agent which is capable of inducing a cellular process, comprising the steps of: 1) determining the effect of one or more agents on a cell unit, comprising the steps of: (a) providing a first set of groups of cell units each comprising one or more cells, and exposing said groups to desired culture conditions; (b) subdividing one or more of said groups to create a further set of groups of cell units; (c) exposing said further groups to further desired culture conditions; (d) optionally, repeating steps (b) - (c) iteratively as required; and (e) assessing the effect on a given cell unit of the culture conditions to which it has been exposed; 2) identifying those agent(s) which induce the desired cellular process in the cell units; and 3) synthesizing or isolating the agent(s).

Group X, claim(s) 30-36, drawn to a method for culturing stem cells or cells that have been derived from stem cells in vitro, comprising the steps of: a) combining one or more cultures of cells grown under different conditions; and b) culturing the cells.

Group XI, claim(s) 37-40, 43 and 44, drawn to a method for culturing stem cells, comprising growing said stem cells adhered to a microcarrier or bead.

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Group XII, claim(s) 41 and 42, drawn to a method for obtaining differentiated cells from stem cells in vitro, comprising the steps of: (a) growing stem cells adherent to microcarriers in a culture medium; (b) transferring the microcarriers from one culture medium to another; (c) optionally repeating step (b) as required; and (d) obtaining the differentiated cells attached to the microcarrier.

Group XIII, claim(s) 45, drawn to a method of growing pluripotent stem cells in vitro comprising the steps of: (a) seeding said cells on microcarriers; and (b) propagating the cells while attached to the carriers.

The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first recited **method**, a method for determining the effect of a plurality of culture conditions on a cell, comprising the steps of: (a) providing a first set of groups of cell units each comprising one or more cells, and exposing said groups to desired culture conditions; (b) subdividing one or more of said groups to create a further set of groups of cell units; (c) exposing said further groups to further desired culture conditions; (d) optionally, repeating steps (b) - (c) iteratively as required; and (e) assessing the effect on a given cell unit of the culture conditions to which it has been exposed. Further pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that any feature which the subsequently recited methods share with the main invention does not constitute a special technical feature within the meaning of PCT rule 13.2 and that each of such methods accordingly defines a separate invention.

The special technical feature of each Group is defined by the distinct steps required by each method.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
6/20/08

/Robert A. Zeman/
for Lakia J. Tongue, Examiner of Art Unit 1645